

February 10, 2023

Vascular Solutions, Inc.  
c/o James Chapman  
Regulatory Affairs Associate  
6464 Sycamore Court  
Minneapolis, Minnesota 55369

Re: K072117

Trade/Device Name: Thrombix™ Patch, Thrombin Hemostasis Patch  
Regulatory Class: Unclassified  
Product Code: QSX

Dear James Chapman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 5, 2007. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSX.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, [Julie.Morabito@fda.hhs.gov](mailto:Julie.Morabito@fda.hhs.gov).

Sincerely,

**Julie A. Morabito -**

**S**

Julie Morabito, Ph.D.

Assistant Director

DHT4B: Division of Infection Control  
and Plastic Surgery Devices

OHT4: Office of Surgical  
and Infection Control Devices

Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Vascular Solutions, Inc.  
% Mr. James Chapman  
Regulatory Affairs Associate  
6464 Sycamore Court  
Minneapolis, Minnesota 55369

OCT 5 2007

Re: K072117

Trade/Device Name: Thrombix™ Patch, Thrombin Hemostasis Patch  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: July 30, 2007  
Received: August 01, 2007

Dear Mr. Chapman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

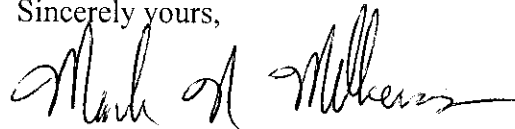
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

Page 2 - Mr. James Chapman

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K072117

Device Name: **Thrombix™ Patch thrombin hemostasis patch**

### Indications for Use:

The Thrombix™ Patch is applied topically and is indicated as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE --  
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K072117

OCT 5 \* 2007

**510(k) Summary**  
(As required by 21 CFR 807.92(c))

510(k) Number: K072117  
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**Date Prepared:** July 30, 2007

**Submitter Information**

Submitter's Name: Vascular Solutions, Inc.  
Address: 6464 Sycamore Court  
Minneapolis, MN 55369

Establishment Registration: 2134812

Contact Person: James Chapman  
Regulatory Affairs Associate  
Phone: (763) 656-4380  
Fax: (763) 656-4253

**Device Information**

Trade Name: Thrombix™ Patch, Thrombin Hemostasis Patch  
Common Name: Topical hemostat  
Classification Name: Unclassified  
Product Code: FRO  
Regulation: Not Applicable

**Predicate Device(s)**

The predicate devices are the currently marketed D-Stat® Dry Topical Hemostat (K030836) and D-Stat® Dry 3x3 (K040510).

**Device Description**

The Thrombix™ Patch thrombin hemostasis patch consists of a lyophilized patch containing bovine derived thrombin as an aid to hemostasis (King Pharmaceuticals license number 0977), sodium carboxymethylcellulose (CMC), and calcium chloride.

The Thrombix™ Patch is applied directly over the source of bleeding, creating a physical barrier to blood flow through the application of adjunctive manual compression. The lyophilized components (thrombin, CMC, and calcium chloride) establish an environment in which a natural blood clot can build and form a physical barrier to bleeding.

The thrombin facilitates hemostasis by enhancing the surface-activated clotting cascade through enzymatic cleavage and conversion of fibrinogen to fibrin.

### **Intended Use/Indications for Use**

The Thrombix™ Patch is applied topically and is indicated as an adjunct to manual compression for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

### **Summary of Non-Clinical Testing**

**The Non-Clinical** Testing included assessment of the physical properties of the Thrombix™ Patch and its ability to achieve its intended use. Bench testing of the physical properties of the Thrombix™ Patch confirmed the suitability of the device for its intended use. The following physical tests were performed:

- Moisture Content Testing  
Thrombin Activity Testing post 4 hours pot-life
- Wetting Time
- pH

A biocompatibility assessment of the device was also performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the device. The device is biocompatible based on the following testing:

- MEM Elution
- Intracutaneous Injection Test
- Systemic Injection Test
- Kligman Skin Sensitization

The results of the tests confirmed the suitability of the device for its intended use.

### **Summary of Clinical Testing**

No human clinical testing was required for this device.

### **Statement of Equivalence**

The Thrombix™ Patch is substantially equivalent to the currently marketed D-Stat® Dry and D-Stat® Dry 3x3 hemostatic bandages based on a comparison of the indications for use and the technological characteristics of the device.

### **Conclusion**

The Thrombix™ Patch is substantially equivalent to the currently marketed D-Stat® Dry and D-Stat® Dry 3x3 hemostatic bandages based on the technological characteristics and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.